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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 16

Application Number: 09/125,329
Filing Date: September 8, 1998
Appellant(s): Portmann et al.

Thomas Hoxie
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed April 19, 2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

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A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection filed on January 19, 2001 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-9, 13, 14, 16-21, 30 and 31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

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199,262	Meier I	10-1986
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4,789,680	Meier II	12-1988
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Munzel I, Progress in Drug Research, vol. 10, pgs. 227-30 (1966).

Munzel II, Progress in Drug Research, vol. 14, pgs. 309-321 (1970).

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Upon reconsideration, the rejection of claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 under 35 U.S.C. 102 and 35 U.S.C. 112 have been withdrawn.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 stand rejected under 35 U.S. 103(a) as being unpatentable over the combined teachings of Meier I, II in view of Munzel I, II.

Meier I, II teach the crystal forms of the instant known compound. Note example 35 of Meier I or example 4 of Meier II. However, Meier I, II does not disclose the lines with interplanar spacings of the X-ray powder pattern of said form or other characterizing parameters thereof, whereas the instant claims disclose specific X-ray diffraction pattern for the claimed compounds. Munzel I, II teach that compounds exist as polymorphs and retain pharmaceutical activity. Hence the claimed crystalline form as well as its relative selectivity of properties, *vis-a-vis* the known compound are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different polymorphic forms.

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Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 14 and 20 of U.S. Patent No. 4,789,680 in view of Munzel I, II.

Meier II '489 discloses the crystal forms of the instant known compound. Munzel I, II teach that the mere existence of further polymorphs of compounds is not itself regarded as unexpected. Hence, patentable distinction is not seen.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 17 and 21-23 of copending Application No. 09/599,688 in view of Munzel I, II.

Ser no. 09/599,688 teaches the crystal form B of the claimed compound. Munzel I, II teach that polymorphs are expected to exist. Hence, the instant crystal form is deemed to be an obvious optional variant of the crystal form B.

This is a provisional obviousness-type double patenting rejection.

(11) Response to Argument

Appellants assert that the Meier references do not suggest or teach the crystalline forms discovered by appellants or a method of making the crystalline forms. It is well known in the art that compounds exist in different crystalline forms. One of ordinary skill in the art would have been motivated to make these crystalline forms with the expectation that they would have better solubility, stability and/or purity. The process by which the different crystalline forms are likewise known in the art. No unexpected or unobvious properties are noted.

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In the predecessor Court, the standard for different physical forms, purity, or other physical characteristics, was set forth in *In re Cofer*, 354 F.2d 664, 148 U.S.P.Q. 268 (CCPA 1966) wherein the differences are rendered obvious by the prior art are not patentable. The beginning of the second series of the U.S.P.Q. since 1983 to the present time, the Court of Appeals for the Federal Circuit has only dealt with one published case dealing with polymorphs and that decision is "*Glaxo Inc. V. Novapharm Ltd.*, 34 U.S.P.Q. 2d, 1565 (Fed. Cir. April 1995)". This decision was drawn to an infringement suit, covered such topics as, Infringement Defenses, Fraud Unclean hands, Patentability, Validity, Best mode, Inequitable Conduct and the like. The issue of obviousness under 35 U.S.C. 103 was not an issue. Yet, the dicta of the Court seemed to indicate that changing the physical forms was not pre se patentable and that objective evidence must be shown in the form of a declaration by applicants clearly showing an unexpected superior result on a side-by-side comparison. Appellants have failed to provide any showing establishing unexpectedly superior results of the claimed crystal form *vis-a-vis* the known compound of Meier I, II. It is known in the prior art that changing solvents with routine experimentation results in different physical forms. Appellants much know that changing physical forms according to legal precedent does not enable applicants "Carte Blanch" when dealing with this type of technology. Otherwise an applicant(s) could extend a monopoly for ever, which is not the intent of the patent.

Appellants in response to the final rejection for the first time submitted two exhibits. Appellants failed to show why they had not been earlier presented. Assuming *arguendo* that

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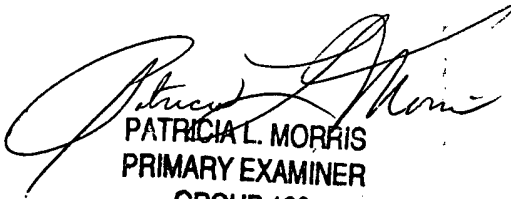
they are indeed proper exhibits, document 1 (CGP 33101) is in German and not in english. The exhibit has not been considered. Document 2 fails to establish any superior unexpected results for the instant crystals *vis-a-vis* the known compound. The instant crystals and the prior art compound are both useful for the treatment of epilepsy. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compound are suggested by the references. It is expected that the instant crystals and prior art compound would be useful for the treatment of epilepsy.

Contra to appellants' arguments regarding the double patenting rejections, appellants have failed to establish any patentable distinction between the crystalline forms, the crystal form B of 09/599,688 or the prior art compound of '489. The absence of evidence concerning the relative properties of the claimed and art compounds does not result in a conclusion that the prima facie obviousness of the claimed compounds has been rebutted. It simply leaves the prima facie obviousness unrebutted. The record herein clearly is not sufficient to permit a conclusion that the claimed crystals are unexpectedly more effective than the reference compounds even for the limited purpose of treating epilepsy.


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For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,


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plm
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